REMARKS

Allowable Subject Matter

In the March 3, 2005 Office Action, Examiner Davis found claims 1-2 and 26-27 to be free of prior art and to meet all requirements of patentability.

Rejections of Claims and Traversal Thereof

In the March 3, 2005 Office Action,

claims 20 and 28 were rejected under 35 U.S.C. §112, first paragraph.

This rejection is hereby traversed, and reconsideration of the patentability of amended claims herein is requested, in light of the ensuing remarks.

Rejection under 35 U.S.C. §112, first paragraph

According to the Office:

> "Since one does not know which fragment of SEQ ID NO: 8 confers induction of cell death, it would be random experimentation to make or screen for the claimed 95% variants, and thus it would be undue experimentation for one of skill in the art to practice the claimed invention."

The test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. See *United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 109 S.Ct. 1954 (1989); *In re Stephens*, 188 USPQ 659, 661 (CCPA 1976). A disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

The Office contends that variants of SEQ ID NO: 8, as recited in claims 20 and 28, do not meet the enablement requirements of 35 U.S.C. §112, first paragraph. Claim 20, as amended, recites as follows:

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20. An isolated variant of SEQ ID NO. 8, wherein the variant is characterized by

(1) at least 95% identity to SEQ. ID NO. 8, wherein all variations in amino acid residues is by conservative substitution;
(2) a conserved carboxy end region having an amino acid sequence of amino acid residues 353 to 405 of SEQ ID NO. 8, and
(3) induces cell death *in vitro*.

According to the Office, "the variants of claims 20, 28 could have deletion or addition at any amino acid, besides conservative substitutions." Applicant has amended the claims thereby obviating this concern by the Office. Clearly, only variants that included conservative substitutions are include in the scope of the claims. Notably, applicant does not believe that this amendment to the claims is necessary, but has conceded to move prosecution forward.

Next, the Office hypothesizes that "one cannot predict whether residues 353-405 could confer or are sufficient to confer the induction of cell death." Initially, it should be noted that the claims recite that the carboxy end must include the residues 353 to 405 and this is a conserved region, which has been recognized by the Office. Just by viewing the conserved regions in Figure 1 provides an indication that the proteins are orthologues (**which are proteins with the same function in the different species**) and proteins from different species are often considered to be orthologous if they detect each other as the best match during (say) Blast searches, having high homology. Clearly, a protein with at **least 95% identity** would be considered to exhibit high homology. One skilled in the art with an undergraduate degree in biology or cell biology has sufficient knowledge and skill to run a Blast program on an amino acid sequence and these actions would not be considered undue experimentation.

The Office further states that it would be undue experimentation to practice the claimed invention because one would have to check if the sequence conferred cell death. Applicant vigorously disagrees because as stated in applicant's last response, determining if a sequence confers cell death is a simple assay test and one skilled in the art can easily perform such a test. Clearly, each step to determine functional variants is not difficult and/or includes undue experimentation. The level of skill of one practicing in this art is very high and with all the tools available to a microbiologist, including all the relevant bioinformatics web sites, one can easily determine if an amino acid sequence fits the criteria set forth in claims 20 and 28.

As stated before, the fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder Co., v. E.I.*

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DuPont de Nemours & Co., 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeal summarized the point well when it stated:

> "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed." *Ex parte Jackson*, 217 USPQ 804, 807 (1982).

Here, all the Office has established is that some experimentation would be required to make and use other embodiments of the claimed invention. The biological activity, that being, the ability to induce cell death can be very easily determined by one skilled in the art, and the specification provides guidance as set forth in Example 2. Thus, the scope of the claims is not broader than that described in the specification and the quantity of experimentation to practice the full scope of the claims does not require undue experimentation.

As stated in applicant's last response, on January 18, 2005, U.S. Patent No. 6,844,323 issued with claims as follows:

We claim:

1. An isolated polypeptide having a calcitonin 11 activity and comprising an amino acid sequence of SEQ ID NO: 2.

2. An isolated polypeptide having a calcitonin 11 activity and comprising an amino acid sequence that is at least 95% identical to SEQ ID NO: 2.

3. A method for detecting a disease related to the polypeptide of claim 2, or for determining a susceptibility of a mammal thereto, said method comprising detecting the amount of expression of said polypeptide, or detecting the activity of said polypeptide.

4. A pharmaceutical composition comprising a polypeptide according to claim 2, and a pharmaceutically acceptable carrier.

* * * * *

Claim 2, as shown above, is even broader than applicant's pending claims 20 and 28 and yet this claim was found patentable with a specification that provides similar guidance to applicant's for practicing the present invention. Applicant is well aware that patentability of a claim is not controlled by the fact that similar claims have been allowed in the Patent Office, since each claim must be patentable in its own right. However, as stated by the Court in *In re Bisley*, 954 USPQ 80, 83 (CCPA 1952) similar claims allowed by the Patent Office Tribunals furnish evidence of what features those tribunals regarded as patentable, and the court determined it was proper and in fact sometimes necessary to consider allowed claims in order to fully determine the views of the board and the examiner. Clearly, Robert Wax, a Primary Examiner for almost thirty years determined that the claims in U.S. Patent No. 6,844,323 were patentable.

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Applicant submits that the instant application provides sufficient and enabling information for a person of ordinary skill in the art to practice applicant's invention and respectfully requests the withdrawal of all rejections under §112, first paragraph.

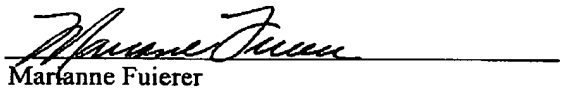
Rejoining of Method Claims

Applicant is reminding the Office that rejoinder was requested early in the prosecution of this application, and as such, is requesting that all method and use claims that are currently withdrawn be rejoined and examined according to the guidelines set forth in Section 821.04 of the MPEP.

Conclusion

Applicant has satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Davis reconsider the patentability of all pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Davis is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,



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